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(54) **Medical appliances for the treatment of blood vessels by means of ionizing radiation**

Arzneigeräte für die Behandlung von Blutgefässen mittels ionisierungsbestrahlung

Appareils médicaux pour le traitement des vaisseaux sanguins à l'aide de radiation ionisante

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(56) References cited:
EP-A- 0 447 745
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Description

[0001] This invention relates to a medical appliance for the treatment of a portion of blood vessel by means of ionizing radiation, comprising a catheter for percutaneous transluminal treatment of the blood vessel, an inflatable dilatation balloon surrounding a portion of the catheter, a radioactive radiation emitter fitting in said portion of the catheter and being radially centered inside the balloon, and means for advancing, resp. removing, the radioactive radiation emitter into, resp. from, the portion of the blood vessel.

[0002] Atherosclerosis causes thickening and hardening of arteries and formation of deposits of plaque or plaque-ridden tissue within the arterial lumen. Such a disease is commonly treated by means of percutaneous transluminal angioplasty techniques involving, i.a., the non-surgical widening of a passage through an artery by means of a balloon inflated to dilate the area of obstruction or the abrasion of the deposits by means of atherectomy. Unfortunately, the major limitation of these angioplasty or atherectomy techniques is the relatively important rate of restenosis. As it has been shown, the balloon angioplasty produces intimal and medial injury leading to excessive platelet aggregation and cell mediators activation followed by an elevated production of myocital growth factors. The cascade of these events, regulated by arterial wall cells nuclei, results in hyperproliferation of smooth muscle cells and migration of myocites and macrophages from the media layer towards the intima and further accelerates excessive neo-intimal formation leading to lumen narrowing. Many approaches to prevent this phenomenon have been tested, among which regimes of anticoagulation, antiplatelet therapy, vasodilators, and serum cholesterol level reducers, however, without appreciable therapeutic effect. As a further approach to this problem, it has been found that ionizing radiation could prove helpful in the treatment of unwanted cell proliferation which causes recurrent stenoses or occlusions after angioplasty.

[0003] The document International Journal of Radiation Oncology Biology Physics, Vol. 24 Suppl. 1, page 171, which reports Proceedings of the 34th Annual ASTRO Meeting of November 1992, refers to a study on the prophylaxis of intimal hyperplasia after stent implantation in peripheral arteries using endovascular irradiation. This study was directed to the frequency of recurrent stenoses or occlusions following stent implantation in peripheral arteries due to rapid intimal hyperplasia. To stop the proliferation of connective tissue an endovascular brachytherapy treatment was performed after percutaneous transluminal angioplasty. The method describes stent implantation after recanalization done by percutaneous transluminal angioplasty, and placing of a 10 Ci Iridium gamma irradiation source into the implanted stent. No specific measures are described which would ensure circumferentially uniform radiation impact on the vessel wall. In this study the radial position of the irradiation source inside the stent was determined by gravity.

[0004] The document JACC Vol. 21 N° 2, February 1993 : 185A, reports a study of the effects of locally delivered ionizing radiation on the proliferation response to balloon overstretching injury. The injury model was balloon angioplasty of the central artery of the ear of rabbit and the ionizing radiation was delivered as high energy beta from a sealed Sr^{90} source in a single dose (skin dose of 900 rad) after a scheduled time delay from the injury. The document further refers to a second protocole using a porcine coronary injury model with transluminal intravascular irradiation. This publication does not disclose any specific measure to ensure an evenly distributed radiation in the vessel.

[0005] US Patent N° 5147282 discloses a manual irradiation loading apparatus particularly suitable for intrabronchial and gynecological irradiation treatment. The apparatus comprises a lead or equivalent radiation shielding body with a longitudinally extending cable-receiving passage therein. A cable having radioactive seeds provided on one end thereof is received in the cable-receiving passage. During storage, the portion of the cable bearing the radioactive source is located in the cable-receiving passage within the shielding body. During use, a catheter placed in a patient is joined to the shielding body and the portion of the cable bearing the radioactive source material is advanced through the cable receiving passage in the shielding body and into the catheter. The radioactive seeds are slidingly positioned inside the catheter, however the radial position of the catheter within the vessel is not controlled.

[0006] US Patent N° 4588395 describes, i.a., a catheter device for generating radioactive radiation into an artery for medicinal or repair purposes. This device comprises a catheter the tubular wall of which is collapsed at its distal end to form a sealing interface closing off the interior volume. Within this volume is located a sort of radioactive pill which can urged forwardly by a piston connected to a flexible shaft controlled at the proximal end of the catheter, forward motion of the piston forcing the pill through the sealing interface in order to protrude from the distal end of the catheter and affect the artery. No means are provided with this catheter to secure a certain predetermined orientation of this catheter inside the geometry of the vessel section.

[0007] In addition to irradiation external to the site, the document Wo 93/04735 also describes an apparatus for the treatment of an artery, comprising a radioactive dose and a means operatively connected to such a radiative dose to bring it into a selected region of an artery. In a first embodiment, the apparatus comprises a sheath removably positioned over a windowed housing containing a radioactive dose and connected to a catheter shaft, whereby the relative motion between catheter shaft and sheath permits moving the windowed housing in and out of the sheath, thereby exposing the

radioactive dose which may affect the selected place in the artery. In a second embodiment, the device comprises a catheter shaft surrounded by an angioplasty balloon on the outer surface of which are affixed radioactive elements intended to be forced into contact with the artery wall upon inflation of the balloon. The balloon has a perfusion channel to allow perfusion of blood f.e. from proximal of the balloon to distal of the balloon. Perfusion of blood is therefore possible even during the phase when the balloon is inflated and normal blood flow is interrupted. A third embodiment, substantially similar to the first one, includes a sheath intended to provide a shielding to a radioactive dose and a motion wire to provide slidable motion of the radioactive dose within the sheath. A fourth embodiment comprises an inflatable stent delivery balloon for expansion of a stent to which a radioactive dose is associated as a cladding, a coating or an additive within the stent material itself. A fifth embodiment shows a shrinkable tubing attached to a catheter shaft and a plurality of radioactive seeds located in the tubing where they are separated from each other by heat shrinking of the tubing which therefore encapsulates the seeds.

[0008] The sheath configuration of the first embodiment suffers from the same drawbacks as the configurations known from the previously mentioned publications. The radial orientation of the radioactive dose inside the vessel is determined by gravity. In the second embodiment, the radioactive elements affixed to the balloon and forced into contact with the artery wall, the radioactive elements provide uniform radiation impact on the artery wall only as far as specifically the area of the individual radioactive element is concerned. A circumferentially uniform radiation on the artery wall is not possible with this configuration. Besides that, the radioactive elements on the outer surface of the balloon are difficult to secure on the flexible balloon surface. Their fixture would have to meet severe safety requirements against loss under all conditions. This would lead to some specific complications. Finally radioactive elements and the fixture of these elements add unfavourably to the deflated profile of the balloon to pass through tight stenoses. The third embodiment with the slidable radioactive dose within the sheath shows the same problems as the first embodiment. It shows no means to control the transversal orientation of the sheath in the vessel. The fourth embodiment, the cladded expanding stent, represents regarding uniformity of radiation the same unfavourable situation as the configuration of the balloon with affixed radioactive elements. Finally, the fifth embodiment adds nothing to the solution of the positioning problem, it mainly refers to the problem of how to safely secure the radioactive seeds to a catheter shaft.

[0009] In all these devices, the radiation cannot be uniform, either because there is absolutely no possibility of having the radioactive element correctly positioned within the artery, or because the radioactive element irregularly bears against the vessel wall.

[0010] The document DE-3620123-A1 discloses an apparatus for measuring and irradiating body cavities which permits the placing and positioning of a light conductor at the center of a cavity in order to achieve homogeneous lighting thereof via a dispersing agent. To this effect, a light conductor is located in a tubular catheter surrounded by two optically transparent centering flexible balloons at a distance from each other and which are inflated by a dispersing agent in order to have them rest against the wall of the body cavity. The portion of the catheter which is located between the balloons is stiffer than the rest of the catheter to avoid modification of the distance between the two balloons, for instance due to curving of the catheter. The system is said to be usable for a blood vessel, but the system needs a dispersing agent and two balloons proximal and distal of the radiation source to accomodate the dispersing agent between the balloons. The two balloons are occlusion balloons. Occlusion balloons have to be resilient to safely fullfill their task in a vessel of unknown exact shape and size. Because of this resiliency, occlusion balloons can not be used simultaneously as dilatation balloons. Resilient balloons would overstretch the vessel wall when used with the higher pressures that are required for a successful angioplasty. Of course the doctor has control over the inflation pressure with resilient balloons same as with dilatation balloons, but this is not sufficient for safe angioplasty. With a resilient balloon the doctor has no control over the inflated diameter or over the shape to which the balloon is inflated.

[0011] DE-U-91 02 312 describes balloon catheters for the treatment of stenoses of blood vessels by means of ionizing radiation; the document also describes irradiation external to the site. In one embodiment, a radioactive seed is affixed to the extremity of a guidewire and merely inserted into the lumen of a balloon catheter without any radial control of its position within the balloon catheter and consequently within the blood vessel; moreover, in a variant of this first embodiment, the catheter lumen is divided by a longitudinal partition wall defining two channels in the catheter lumen and the seeded guidewire is inserted into one of these channels in a radially offset position with respect to the balloon; there is absolutely no possibility of having the radioactive element correctly positioned within the, and the radiation cannot be circumferentially uniform along the vessel wall. In a second embodiment, the radioactive source is located in a channel centered in the balloon catheter by two longitudinally extending radial walls or wings; such radial walls or wings cause an uncontrollable deformation of the presumably centered channel upon inflation of the balloon, whereby there is full uncertainty as to the positioning of the radioactive element within the blood vessel; furthermore, with the balloon in deflated condition, the flexibility of the catheter is not uniform in all bending directions with respect to the longitudinal axis thereof, and this results in bad handling

qualities for the balloon catheter; in addition, the radial walls or wings are material and place consuming, and the balloon catheter becomes difficult to manufacture and bulky which makes it inappropriate for use in narrow stenoses or tortuous configurations of the blood vessels. A third embodiment comprises a two balloon configuration arranged on a catheter the lumen of which is provided with a central channel positioned in the catheter lumen by four longitudinally extending radial walls, whereby the central channel is surrounded by four channels, two of which are used for independently inflating the balloons, and the two others are used for flooding the portion of the blood vessel located between the balloons; a radioactive source may be located either in one of the flooding channels or in the central channel; the two balloon configuration deforms the portion of the catheter which is located between the balloon and this adds to the uncontrollable deformation of the central channel resulting from the radial walls used to position the central channel; where the radioactive source is located in the central channel, there cannot be any certainty as to its final position in the blood vessel; where the radioactive source is located in the flooding channel, the radioactive source is radially offset with respect to the balloon, which certainly will not reduce the uncertainty as to its final positioning in the blood vessel; furthermore, this construction multiplies the material and place consumption of the second embodiment, with the resulting difficulties of manufacture and bulkiness inappropriate for narrow or tortuous areas of the blood vessel. It may be noted that this document outlines that for both the second and third embodiments, it is envisaged to push the radioactive element out of the central channel to place it directly within a stenosis, which eliminates any idea of centering the radioactive element in the blood vessel.

[0012] US-A-5106360 discloses a thermotherapeutic apparatus comprising an applicator for insertion in a body cavity. In a first embodiment, the applicator includes a multilumen tube surrounded by an inflatable balloon. In one of the lumens is a power cable leading to a coil shaped electrode surrounding the catheter within the balloon. In another lumen is arranged a radioactive radiation source which is radially offset with respect to the balloon, whereas a circumferentially uniform radiation of a vessel is not possible, the system may be subjected to uncontrollable deformation upon expansion of the balloon, and it is too bulky for usage in narrow blood vessel. In a second embodiment, a second balloon is interposed between the coil electrode and the balloon, so that a liquid radiation source may be injected within the second balloon; eventhough the liquid source extends circumferentially around the multilumen tube, the system is subject to uncontrolled deformation upon expansion of the balloons; it is also too bulky for proper operation in a blood vessel, and it is open to the risk of the radioactive liquid getting lost in a blood vessel in case of balloons becoming untight.

[0013] EP-A-0 447 745 shows a device for body cavity treatment by means of radioactive radiation. This device comprises a feeding pipe for a radioactive emitter mounted on a cable movable in the feeding pipe; the feeding pipe is arranged with play in an elastically deformable pipe whereby the two pipes have axial mobility with respect to one another; an end piece locks the distal ends of both the feeding pipe and the elastic pipe to one another; the elastic pipe is longitudinally slotted whereby the elastic pipe forms an expandable head upon relative motion of the feeding pipe into the elastic pipe. Such a configuration may be used for some positioning of the system in large body cavities such as air-vessels. However, the slotted elastically expandable pipe cannot do more than a very rough positioning of the radioactive emitter because the expansion strips resulting from the slotted configuration cannot be controlled, either as regards the expanded diameter, or as regards the shape to which the system expands, or still as regards their longitudinal positioning. The system could therefore not be used for a precise and uniform irradiation of blood vessels.

[0014] GB-A-793 158 shows a device for the treatment of body cavities by means of radioactive radiation. In one embodiment, an inflatable bulb is formed of two layers of rubber material between which is positioned a layer of radioactive material; the bulb is tightly affixed on a two tube arrangement allowing for fluid intake into the bulb by inflation thereof and for intake and evacuation of the fluids within the body cavity. In a second embodiment, the structure is the same except that the radioactive material is located on a part only of the bulb. The first embodiment may allow a circumferentially uniform radiation, however, its manufacture may prove difficult while the activation of the radioactive material dangerously affects the whole equipment; and the system is necessarily bulky because the radiation material adds to the deflected profile of the bulb. The second embodiment has the same problems, in addition to the fact that the radiation can definitely not be uniform on the body cavity. In addition, for both embodiments, any defect in the tightness of the bulb induces a strong risk of having the radioactive material getting lost in the body cavity. The system thus is not applicable to percutaneous transluminal treatment of a blood vessel.

[0015] The document US-A-5 199 939 describes an elongated flexible catheter with radioactive means located in a distal section thereof. In this structure the radial position of the irradiation source inside the vessel is determined by gravity whereby the radiation cannot be uniform and there is absolutely no possibility of having the radioactive element correctly positioned within an artery.

[0016] The purpose of this invention is to improve the conditions of radioactive radiation treatment of blood vessels stenoses due to excessive intimal formation by proposing a medical appliance with dilatation balloon or with perfusion channel for a vessel wall radiation which

is uniform around the circumference of the vessel, an appliance that is simple to manufacture and easy to use, that allows traversal of narrow stenoses and that allows safe securing of the radioactive emitter to its advancing resp. removing means.

[0017] To this effect, the invention complies with the definitions given in the claims.

[0018] In that way, it becomes possible to improve dosage control of the radioactive radiation with regard to distance between the radioactive source and the vessel wall, respectively with regard to distance between radioactive source and vessel wall and timing during which the radioactive treatment has to be applied.

[0019] Specifically the essentially centered emitter ensures essentially equal radial distance to all segments of the vessel wall so that a pattern of areas with overdosage because of too narrow distance and areas with underdosage because of too wide distance to the vessel wall is avoided. The impact of radiation on the vessel wall is circumferentially essentially uniform.

[0020] As the medical appliance comprises a dilatation balloon, dilatation and radioactive treatment can be performed in one procedure. The cure for the vessel wall proliferation can be taken immediately with the cause for the vessel wall proliferation. This also has the advantage of an optimum automatic match between the location in the vessel where the cure is taken and the location in the vessel where the cause is laid. If during the procedure the dilatation balloon is not shifted inside the vessel, the radiation treatment will automatically be in the exact place where it is needed, unintentional exposure of undilated vessel portions to radiation is reduced.

[0021] If the medical appliance comprises a perfusion channel, the blood flow in the radiated vessel is not totally cut off during the time of exposure to radiation. That means, that ischemia in the areas lying in the blood flow direction behind the treatment site and the dangerous consequences of ischemia for example in coronary arteries are reduced. The radiation can with a perfusion channel be extended longer without these negative consequences and that again allows the use of an emitter with relatively low radiation density which will have less unintended side effects during the rest of the treatment procedure.

[0022] If the centered emitter is movable within the catheter, this allows specifically a quick and safe method of use for the appliance. The emitter then can be traversed to the place of treatment simply by sliding it forward inside the catheter. This ensures an easy and quick handling of the device and specifically makes sure that the vessel path from the percutaneous vessel entrance to the exact position of the treatment place is not unintentionally overexposed to radiation due to slow advance speed of the emitter and that the exact exposure times for the radiation at the treatment site can reliably be observed. Also the vessel wall is saved from unnecessary mechanical stress from the advancement of the device. The potentially time consuming exact location of the treatment site with the medical appliance within the branched vessel system is in this case not done under radiation.

[0023] Preferably the radioactive radiating emitter is selected from the group of beta emitters. Beta emitters have a relatively short half-life. This is desirable to allow procedure times that are manageable in interventional medicine. Also the high radiation activity per specific gravity of beta emitters leads to small dimensions for the emitter which is very important in interventional techniques. Furthermore the travel distance of beta radiation inside the tissue is very short. This is very favourable for the treatment here in question. To interrupt the mechanism that lead to tissue proliferation, radiation of the surface of the vessel wall is sufficient. Radiation that travels deep into the tissue is undesirable and induces side effects. Furthermore, beta radiation needs no heavy shielding like lead or concrete. A beta radiation emitter can be shielded with plastic shieldings of practicable thicknesses so that beta emitters can be transported and handled with relatively low additional safety precautions compared to usual non-radiating products and shielded beta emitters are not bulky or heavy. Specifically the treatment room where the procedure is carried out needs no specific reinforcement in concrete, lead or other material. It is practically most important, that with the use of beta emitters the doctor can stay in the room were the treatment is made, he can directly carry out the treatment. The use of beta emitters therefore allows this treatment to be implemented in any arbitrary hospital without specific prior local precautions at the hospital itself.

[0024] The use of an emitter in form of a filament has the advantage, that the emitter can be safely fixed to the positioning means without the risk of any part of the emitter getting lost or without the risk of a container becoming untight, being thus safer than seeds or powder or other forms. In addition, a further advantage of the filament is dens concentration of dose in a small diameter.

[0025] Preferably the beta emitter is of 90 Yttrium which has a half-life of 2.7 days, a middle energy 0.942 Mev and maximal energy of 2.28 Mev, which would allow appreciable irradiation within a short distance from the filament, whereby only the internal layers of the vessel wall will be heavily irradiated while the more external structures will receive a dose which decreases with the square of the distance. Yttrium can be made available in form of filaments, so that with the selection of Yttrium the advantages of beta emitters and of filament emitters are available.

[0026] Because of its mechanical characteristics, the filament of 90 Yttrium can have a diameter equal to or less than 0.9 mm. An emitter of this dimension is specifically suitable for percutaneous transluminal procedures.

[0027] Subject to a heat elaboration under vacuum to

avoid rapid oxydation and the resulting risk of breaking, the filament of 90 Yttrium can even have a diameter equal or less than 0.2 mm. An emitter of this dimension can be introduced into the guidewire lumen of such percutaneous transluminal devices that have a very small deflated or folded profile. Such devices can use introducer sets with small outer diameter and low trauma at the percutaneous introduction site and inside the vessel such devices can cross very narrow stenoses.

[0028] If the emitter is coiled around the guide wire, this has the advantage, that an easy to accomplish and safe fixture is achieved. It can be made in a simple procedure, which is possible even under shielding conditions and thus can be made after the emitter has been activated. This is advantageous because a fixture to the guide wire before the activation of the emitter brings the problem of partially activating the guide wire together with the activation of the already affixed emitter.

[0029] Even only partly activation of the guide wire material might induce already unfavourable effects in this material, f.e. gamma radiation.

[0030] A preferred approach is to make use of a guide wire of titanium which, after activation in a powerful field of neutrons, will have a decay time of 5.8', and will advantageously solve the problem of undesirable long living of isotopes induction in other guide wires while providing mechanical qualities equivalent to those of stainless steel. Therefore with a titanium wire as carrier for the emitter, the emitter can be affixed to the carrier before the emitter is activated without any practical risk of radiation pollution. This brings the great advantage that the affixing procedure can be made under normal conditions without any radioactive shielding for the involved persons. Also in this configuration the emitter needs not to be separated again from the guide wire for reactivation of the emitter when the activity of the emitter is consumed.

[0031] These and other objects will become readily apparent from the following detailed description with reference to the accompanying drawings which show, diagrammaticaly and by way of example only, three embodiments of the invention.

Fig. 1 is an axial cut of the first embodiment.

Fig. 2 is an axial cut of the second embodiment.

Fig. 3 is an axial cut of the third embodiment.

[0032] In all the embodiments shown only the portions which have to be located in a blood vessel stenosis have been depicted; the other portions of the embodiments shown may be devised as currently practised in the art. Similarly, no particular shielding equipment for storage and transit of radioactive materials is being discussed here, reference being solely made in this respect to known techniques such as for instance those described in US Patent N° 5147282.

[0033] The first embodiment of Fig. 1 comprises a flexible catheter tube 1 in which is centered a guide wire 2 with a tip 3, said guide wire being in sliding fit within the catheter tube 1. A substantially cylindrical dilatation balloon 5 is mounted coaxially on the catheter tube 1 to which it is affixed annularly by its ends. The catheter 1 is a two lumen catheter in which the second lumen 6 acts as an inflation tube for the balloon 5. This balloon 5 is shown in inflated condition at the location of a stenosis (not shown) of a blood vessel 7, for instance a coronary artery. A radioactive radiation emitter in the form of a filament 4 is integrated into the guide wire 2 inside the balloon 5, this radioactive filament 4 being thus essentially centered in the balloon at the location of its dilatation in the blood vessel. The radioactive radiation of the filament 4 is thus applied uniformly to the dilated stenosis due to the centering achieved by the sole dilatation balloon 5, which would result in optimal dosimetric homogeneity of the irradiation procedure. The term essentially centered for the position of the emitter inside the balloon or inside the blood vessel is used in this document to describe configurations which in normal use do not lead to alternating segments along the vessel wall circumference with unsufficiently treated cell proliferation on one side and unnecessary radioactive overdosis on the other side. This use of the term essentially centered therefore includes configurations in which the emitter in use is secured in a predetermined position in the vessel section and in which this position is spaced from the vessel wall but in which the emitter is not held in the precise center of the medical device or the vessel section but is held somehow decentered and in which despite of such decentralisation of the emitter, the treatment results that are achieved with the device are still satisfactory from a medical point of view.

[0034] The embodiment of Fig. 2 comprises the basic configuration of the first embodiment of Fig. 1 with an added perfusion capacity via holes 8 and 9 respectively arranged in the wall of the catheter 10 before and after the balloon 5. The radioactive filament 40 is affixed to the distal end of the guide wire 2. In addition to the balloon centering and resulting uniform irradiation achieved by the embodiment of Fig. 1, this embodiment permits maintaining the irradiation for a substantially longer time as blood flow is no more hindered by the balloon. It also permits to place the radioactive emitter at the level of angioplasty without getting the distal part of the guide wire out of the catheter.

[0035] The embodiment of Fig. 3 combines the basic configurations of the embodiments of Figs. 1 and 2 except that in this embodiment the filament 45 is coiled around the guide wire 2 to facilitate assembly thereof.

[0036] In all the embodiments shown, the guide wire and radioactive emitter may be fixed to the catheter instead of being movable within the catheter. As a further development, the catheter may comprise a guide wire for conventional entry into the blood vessel and the radioactive radiation emitter may be a filament affixed to

or coiled around a wire intended to replace the said guide wire.

[0037] The radioactive radiation emitter can be under any appropriate form as described. Filaments will be however preferred because they can be safely fixed to the positioning means without the risk of any part of the emitter getting lost or without the risk of a container becoming untight, being thus safer than seeds or powder or other forms. In addition, a further advantage of the filament is dens concentration of dose in a small diameter.

[0038] The radioactive radiation emitter can be selected at will, preferably however among beta emitters with a relatively short half-life, optimal penetration characteristics in tissue, and with a high radiation activity per specific gravity of the emitter ($Bq/mg/mm^3$).

[0039] More specifically, a preferred choice will be a filament of 90 Yttrium which has a half-life of 2.7 days, a middle energy 0.942 Mev and maximal energy of 2.28 Mev, which would allow appreciable irradiation within a short distance from the filament, whereby only the internal layers of the vessel wall will be heavily irradiated while the more external structures will receive a dose which decreases with the square of the distance. Because of its mechanical characteristics, the filament of 90 Yttrium can have a diameter equal to or less than 0.9 mm. Subject to a heat elaboration under vacuum to avoid rapid oxydation and the resulting risk of breaking, the filament of 90 Yttrium can even have a diameter equal or less than 0.2 mm.

[0040] As described, the filament may be coiled around a guide wire or otherwise affixed to the guide wire in order to be integrated therewith. Accordingly, the filament may be for example welded to the guide wire.

[0041] A preferred approach is to make use of a guide wire of titanium which, after activation in a powerful field of neutrons will have a decay time of 5.8', and will advantageously solve the problem of undesirable long living of isotopes induction in other guide wires while providing mechanical qualities equivalent to those of stainless steel. In this environment, the filament will be either straight and affixed to the guide wire or coiled around the wire.

[0042] Although the balloon of the embodiments of Figs. 1 to 3 has been shown and described as being substantially cylindrical and annularly affixed by its ends to the catheter, other known shapes and catheter fixing for the balloon are possible.

Claims

1. A medical appliance for the treatment of a portion of blood vessel (7) by means of ionizing radiation, comprising a catheter (1, 10) for percutaneous transluminal treatment of the blood vessel, an inflatable dilatation balloon (5) surrounding a portion of the catheter, a radioactive radiation emitter (4, 40, 45) fitting in said portion of the catheter and being radially centered inside the balloon, and means (1, 2, 10) for advancing, resp. removing, the radioactive radiation emitter into, resp. from the portion of the blood vessel, characterized in that the catheter (1) is a two lumen catheter, the portion of the catheter surrounded by the balloon (5) is a single lumen catheter, and the dilatation balloon (5) is mounted coaxially on said portion of the catheter (1) for radially centering the radioactive radiation emitter inside the balloon at the location of dilatation thereof in the blood vessel.

2. A medical appliance according to claim 1, wherein the radioactive radiation emitter (4, 40, 45,) is movable within the catheter (1, 10).

3. A medical appliance according to any preceding claim, wherein the balloon (5) is substantially cylindrical and annularly affixed by its ends to the catheter.

4. A medical appliance according to any preceding claim, wherein the catheter (10) comprises a perfusion channel connected to openings (8, 9) in the catheter wall before and after the balloon (5).

5. A medical appliance according to any preceding claim, wherein the catheter is a catheter for percutaneous transluminal angioplasty.

6. A medical appliance according to any preceding claim, wherein the radioactive radiation emitter (4, 40, 45) is a beta radiation emitter.

7. A medical appliance according to any preceding claim, wherein the radioactive radiation emitter (4, 40, 45) is a filament.

8. A medical appliance according to claim 6 or 7, wherein the radioactive radiation emitter (4, 40 45) is of 90 Yttrium.

9. A medical appliance according to claim 6, wherein the radioactive radiation emitter (4, 40, 45) is a filament of 90 Yttrium with a diameter equal to or less than 0.9 mm.

10. A medical appliance according to claim 6, wherein the radioactive radiation emitter (4, 40, 45) is a filament of 90 Yttrium which is heat elaborated under vacuum.

11. A medical appliance according to claim 9 or 10, wherein the filament has a diameter equal to or less than 0.2 mm.

12. A medical appliance according to any preceding claim, wherein the catheter comprises a guide wire

(2) in sliding fit therein, and wherein the radioactive radiation emitter is a filament (4, 40, 45) affixed to said guide wire.

13. A medical appliance according to any of claims 1 to 11, wherein the catheter comprises a guide wire (2) in sliding fit therein, and wherein the radioactive radiation emitter is a filament (45,) coiled around the said guide wire.

14. A medical appliance according to any of claims 1 to 11, wherein the catheter comprises a guide wire in sliding fit therein, and wherein the radioactive radiation emitter (4, 40, 45) is a filament affixed to a wire intended to replace the said guide wire.

15. A medical appliance according to any of claims 1 to 11, wherein the catheter comprises a guide wire in sliding fit therein, and wherein the radioactive radiation emitter (45) is a filament coiled around a wire intended to replace the guide wire.

16. A medical appliance according to any of claims 12 to 15, wherein the radioactive radiation emitter is a filament affixed to a wire of titanium.

17. A medical appliance according to any of claims 12 to 15, wherein the radioactive radiation emitter is a filament coiled around a wire of titanium.

Patentansprüche

1. Medizinisches Gerät für die Behandlung eines Teils des Blutgefäßes (7) mittels ionisierender Strahlung, das einen Katheter (1, 10) für die perkutane transluminale Behandlung des Blutgefäßes, wobei ein aufblasbarer Dilatationsballon (5) einen Teil des Katheters umgibt, einen radioaktiven Strahler (4, 40, 45), der in den Teil des Katheters paßt und radial im Ballon zentriert ist, und Mittel (1, 2, 10) zum Vorwärtsbewegen bzw. Entfernen des radioaktiven Strahlers in den bzw. aus dem Teil des Blutgefäßes umfaßt, dadurch gekennzeichnet, daß der Katheter (1) ein zweilumiger Katheter ist, der vom Ballon (5) umgebene Teil des Katheters ein Katheter mit einem Lumen ist und der Dilatationsballon (5) koaxial am Teil des Katheters (1) zum radialen Zentrieren des radioaktiven Strahlers im Ballon an der Stelle seiner Dilatation im Blutgefäß angebracht ist.

2. Medizinisches Gerät nach Anspruch 1, wobei der radioaktive Strahler (4, 40, 45) im Katheter (1, 10) beweglich ist.

3. Medizinisches Gerät nach einem der vorangegangenen Ansprüche, wobei der Ballon (5) im wesentlichen zylindrisch ist und an seinen Enden ringförmig am Katheter befestigt ist.

4. Medizinisches Gerät nach einem der vorangegangenen Ansprüche, wobei der Katheter (10) einen Durchströmungskanal umfaßt, der mit Öffnungen (8, 9) in der Katheterwand vor und nach dem Ballon (5) verbunden ist.

5. Medizinisches Gerät nach einem der vorangegangenen Ansprüche, wobei der Katheter ein Katheter für die perkutane transluminale Angioplastie ist.

6. Medizinisches Gerät nach einem der vorangegangenen Ansprüche, wobei der radioaktive Strahler (4, 40, 45) ein β-Strahler ist.

7. Medizinisches Gerät nach einem der vorangegangenen Ansprüche, wobei der radioaktive Strahler (4, 40, 45) ein Faden ist.

8. Medizinisches Gerät nach Anspruch 6 oder 7, wobei der radioaktive Strahler (4, 40, 45) aus 90 Yttrium besteht.

9. Medizinisches Gerät nach Anspruch 6, wobei der radioaktive Strahler (4, 40, 45) ein Faden aus 90 Yttrium mit einem Durchmesser von gleich oder weniger als 0,9 mm ist.

10. Medizinisches Gerät nach Anspruch 6, wobei der radioaktive Strahler (4, 40, 45) ein Faden aus 90 Yttrium ist, der unter Vakuum hitzebehandelt wurde.

11. Medizinisches Gerät nach Anspruch 9 oder 10, wobei der Faden einen Durchmesser von gleich oder weniger als 0,2 mm aufweist.

12. Medizinisches Gerät nach einem der vorangegangenen Ansprüche, wobei der Katheter einen Führungsdraht (2) umfaßt, der darin gleitend paßt, und wobei der radioaktive Strahler ein Faden (4, 40, 45) ist, der am Führungsdraht befestigt ist.

13. Medizinisches Gerät nach einem der Ansprüche 1 bis 11, wobei der Katheter einen Führungsdraht (2) umfaßt, der darin gleitend paßt, und wobei der radioaktive Strahler ein Faden (45) ist, der um den Führungsdraht gewunden ist.

14. Medizinisches Gerät nach einem der Ansprüche 1 bis 11, wobei der Katheter einen Führungsdraht umfaßt, der darin gleitend paßt, und wobei der radioaktive Strahler (4, 40, 45) ein Faden ist, der an einem Draht befestigt ist, der den Führungsdraht ersetzen soll.

15. Medizinisches Gerät nach einem der Ansprüche 1

bis 11, wobei der Katheter einen Führungsdraht umfaßt, der darin gleitend paßt, und wobei der radioaktive Strahler (45) ein um den Draht gewundener Faden ist, der den Führungsdraht ersetzen soll.

16. Medizinisches Gerät nach einem der Ansprüche 12 bis 15, wobei der radioaktive Strahler ein an einem Titandraht befestigter Faden ist.

17. Medizinisches Gerät nach einem der Ansprüche 12 bis 15, wobei der radioaktive Strahler ein um einen Titandraht gewundener Faden ist.

Revendications

1. Appareil médical pour le traitement d'une partie d'un vaisseau sanguin (7) au moyen d'une radiation ionisante, comprenant un cathéter (1, 10) pour un traitement transluminal percutané du vaisseau sanguin, un ballon de dilatation gonflable (5) qui entoure une partie du cathéter, un émetteur de radiation radioactive (4, 40, 45) qui s'emboîte dans ladite partie du cathéter et qui est centré radialement à l'intérieur du ballon et un moyen (1, 2, 10) pour faire avancer, respectivement enlever, l'émetteur de radiation radioactive dans, respectivement depuis, la partie du vaisseau sanguin, caractérisé en ce que le cathéter (1) est un cathéter à deux lumières, la partie du cathéter entourée par le ballon (5) est un cathéter à une seule lumière et le ballon de dilatation (5) est monté de façon coaxiale sur ladite partie du cathéter (1) pour centrer radialement l'émetteur de radiation radioactive à l'intérieur du ballon à l'endroit de sa dilatation dans le vaisseau sanguin.

2. Appareil médical selon la revendication 1, dans lequel l'émetteur de radiation radioactive (4, 40, 45) peut être déplacé à l'intérieur du cathéter (1, 10).

3. Appareil médical selon l'une quelconque des revendications précédentes, dans lequel le ballon (5) est sensiblement cylindrique et est fixé annulairement au moyen de ses extrémités sur le cathéter.

4. Appareil médical selon l'une quelconque des revendications précédentes, dans lequel le cathéter (10) comprend un canal de perfusion connecté à des ouvertures (8, 9) ménagées dans la paroi du cathéter avant et après le ballon (5).

5. Appareil médical selon l'une quelconque des revendications précédentes, dans lequel le cathéter est un cathéter pour une angioplastie transluminale percutanée.

6. Appareil médical selon l'une quelconque des revendications précédentes, dans lequel l'émetteur de radiation radioactive (4, 40, 45) est un émetteur de radiation bêta.

7. Appareil médical selon l'une quelconque des revendications précédentes, dans lequel l'émetteur de radiation radioactive (4, 40, 45) est un filament.

8. Appareil médical selon la revendication 6 ou 7, dans lequel l'émetteur de radiation radioactive (4, 40, 45) est en yttrium 90.

9. Appareil médical selon la revendication 6, dans lequel l'émetteur de radiation radioactive (4, 40, 45) est un filament en yttrium 90 présentant un diamètre égal ou inférieur à 0,9 mm.

10. Appareil médical selon la revendication 6, dans lequel l'émetteur de radiation radioactive (4, 40, 45) est un filament en yttrium 90 qui est élaboré à chaud sous vide.

11. Appareil médical selon la revendication 9 ou 10, dans lequel le filament présente un diamètre égal ou inférieur à 0,2 mm.

12. Appareil médical selon l'une quelconque des revendications précédentes, dans lequel le cathéter comprend un fil de guidage (2) emboîté dedans de façon coulissante et dans lequel l'émetteur de radiation radioactive est un filament (4, 40, 45) fixé sur ledit fil de guidage.

13. Appareil médical selon l'une quelconque des revendications 1 à 11, dans lequel le cathéter comprend un fil de guidage (2) emboîté dedans de façon coulissante et dans lequel l'émetteur de radiation radioactive est un filament (45) bobiné autour dudit fil de guidage.

14. Appareil médical selon l'une quelconque des revendications 1 à 11, dans lequel le cathéter comprend un fil de guidage emboîté dedans de façon coulissante et dans lequel l'émetteur de radiation radioactive (4, 40, 45) est un filament fixé sur un fil destiné à remplacer ledit fil de guidage.

15. Appareil médical selon l'une quelconque des revendications 1 à 11, dans lequel le cathéter comprend un fil de guidage emboîté de façon coulissante dedans et dans lequel l'émetteur de radiation radioactive (45) est un filament bobiné autour d'un fil destiné à remplacer le fil de guidage.

16. Appareil médical selon l'une quelconque des revendications 12 à 15, dans lequel l'émetteur de radiation radioactive est un filament fixé sur un fil en titane.

17. Appareil médical selon l'une quelconque des revendications 12 à 15, dans lequel l'émetteur de radiation radioactive est un filament bobiné autour d'un fil en titane.

FIG.1

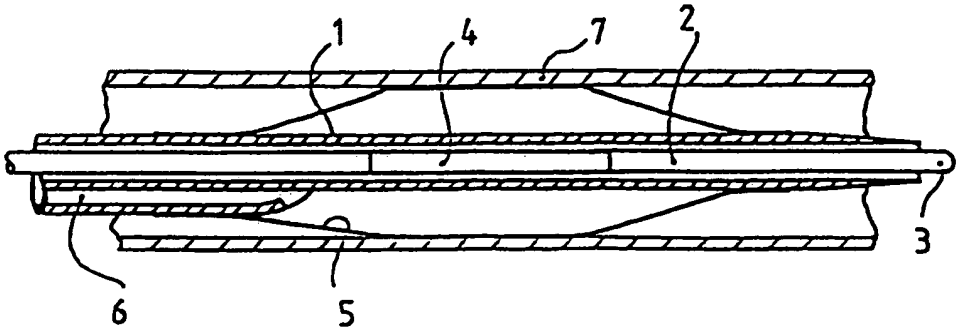

FIG. 2

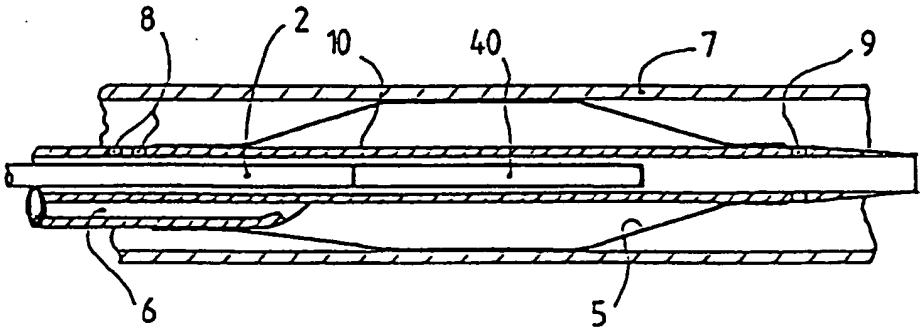

FIG. 3